

### **REMARKS**

Claims 42, 43, 45-49, 53-59, and 61 are pending. As disclosed herein, Claim 42 is currently amended. Support for newly amended Claim 42 can be found in the specification of the instant Application at *e.g.*, paragraphs [0074] and [0098]. No new matter has been introduced. Applicant respectfully requests reconsideration of the claims in light of the following arguments. Applicant believes that the Application is in a condition for allowance.

### **Claim Rejections – 35 U.S.C. § 103**

Claims 42, 43, 45-46, 49, 54, 57-59, and 61 were rejected under 35 U.S.C. § 103(a) as unpatentable over Liu (U.S. Patent No. 6,045,791) in view of Dutt et al. (1991; IDS ref. #15). The Examiner stated that Liu teaches a method of treating a retinal disorder such as age-related macular degeneration, by transplanting retinal pigment epithelial (RPE) cells cultured on an attachment substrate into the subretinal area of a patient in need thereof, although it does not teach the use of an amniotic membrane. Further according to the Examiner, Dutt et al. teaches the use of human amniotic membrane as a substrate for culturing RPE cells. The Examiner felt that therefore a skilled artisan would have been motivated to replace the collagen substrate of Liu with the amniotic membrane of Dutt et al. in the method of Liu, since both substrates are considered art-recognized equivalents for growing RPE cells for transplantation.

Applicants respectfully traverse Examiner's § 103 rejection for the following reasons. Newly amended Claim 42 claims a method for treating a retinal disease, comprising inserting in a subretinal space of a patient in need thereof a composite comprising amniotic membrane and *confluent* retinal pigment epithelial cells or *confluent* retinal pigment epithelial equivalent cells on the membrane. Thus, Claim 42 as amended requires that the RPE or RPE equivalent cells retain the ability to grow until they reach confluency on the membrane.

One of skill in the art would not combine Liu in view of Dutt et al. to achieve confluence of the RPE or RPE equivalent cells on the membrane required by Claim 42, because one would not recognize the amniotic membrane of Dutt et al. as an art-recognized equivalent for the collagen substrate of Liu. The method of Liu requires that the RPE cells be maintained in culture conditions for growth of RPE cells, while the amniotic membrane of Dutt et al. cannot achieve such growth.

Liu requires that the RPE cells be “apposed to a substrate to which they will attach and grow, and which is capable of being maintained in culture conditions appropriate for efficient growth of RPE cells.” (Liu at 7:65-8:1) However, Dutt et al. explicitly teaches that its amniotic membrane substrates *inhibited cell growth*. (Dutt et al. at 1093, 1098-99) Because the growth inhibitory effects of the amniotic membrane of Dutt et al. were “quite evident,” Dutt et al. would not be able to resolve the deficiencies of Liu to achieve the cell growth necessary to achieve confluency of RPE or RPE equivalent cells on the amniotic membrane as required by Claim 42.

In sum, the scope of amended Claim 42 extends beyond the teaching of Liu in view of Dutt et al., because Dutt et al. in combination with Liu would not be able to achieve the confluency of RPE or RPE equivalent cells required by Claim 42. Because a person of ordinary skill in the art would not recognize the amniotic membrane of Dutt et al. as an art-recognized equivalent to the collagen substrate of Liu for growing RPE or RPE equivalent cells for transplantation, Applicant respectfully submits that the invention as a whole would not have been prima facie obvious to a person of ordinary skill at the time the invention was made over Liu in view of Dutt et al. Because Claim 42 is not obvious by Liu in view of Dutt et al., dependent claims 43, 45-46, 49, 54, 57-59, and 61 are also non-obvious, and withdrawal of each rejection is earnestly requested.

**CONCLUSION**

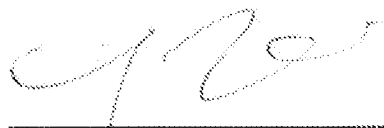
Applicant submits that this paper fully addresses the Office Action mailed November 9, 2007. Applicants respectfully solicit the Examiner to expedite prosecution of this patent application to allowance. Should the Examiner have any questions, the Examiner is encouraged to contact the undersigned attorney at (858) 350-2306. The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 34157-707.831).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Date: November 28, 2007

By:



Michael J. Hostetler  
Attorney for Applicants  
Registration No. 47,664

650 Page Mill Road  
Palo Alto, CA 94304  
Direct Dial: (858) 350-2306  
Customer No. 021971